510(K) SUMMARY

[as required by 807.92(c)]

JAN 18 2011

A.510k Number:

B. Applicant: C ompany name: PATS CORP
Address: 49 Candlewood Way, Buena Park, CA 90621, USA
Phone: 714-523-1592
FAX: 714-523-1592

C. Proprietary and Established Names: **Shanghai APOLO Medical Technology Co., Ltd**
Address: 3/F, Building A, No. 388, Yindu Road, Xuhui District,Shanghai, China
Tel: +86-21-3462 2842
Fax: +86-21-3462 2840

D. Regulatory Information

Common Name: Intense Pulsed Light (IPL) system.

Classification name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR Part 878.4810).

Device classification: Class II.

Product code: GEX

E. Intended use

iPulseLight IPL System (HS 300C, HS 650) are identical with regard to indications for use including recommended filters to be used with Fitzpatrick skin type. Both models are intended for medical use in the treatment of the following dermatologic conditions:

· Permanent hair reduction- long-term stable reduction in number of hairs re-growing after a treatment regimen.

· Treatment of:

- Moderate inflammatory acne vulgaris
- Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles).
- Cutaneous lesions including scars
- Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, leg veins,

spider anglomas and venous malformations.

The integrated thermal cooling is indicated for use in cooling the epidermis at the treatment site prior to, during, and after light treatment in general aesthetic dermatologic and plastic surgery procedures.

- Reduce pain during light treatment (via partial anesthesia from cooling)
- Reduce discomfort during and/or associated with light treatment
- Minimize thermal injury, including thermal necrosis, to non-target skin and skin s tructures during and/or associated with light treatment, thus reducing possible complications such as scabbing, scarring, hyper - and/or hypo pigmentation
- Allow the use of higher light or laser fluencies for light treatments (such as for hair removal and the treatment of vascular or pigmented lesions)
- Reduce potential side effects of light treatments (such as for hair removal and the treatment of vascular or pigmented lesions)

F. Description

iPulseLight IPL System is a type of intensive, broadband, coherent light source which has a wavelength spectrum of 420 nm -1200 nm. With these special properties, the IPL has a wide application in non-ablative therapies based on theory of human skin tissue's selective absorption and photothermolysis of light sources. Meanwhile, IPL treatment is more effective, with no downtime and can make the patients get recovered more quickly than conventional therapies.

G. Substantial Equivalence Information

Classification name: Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810).
Device classification: C lass II.
Product code: GEX
Predicate devices: Accelawave System (K082484)

Comparison of Ellipse I PL to predicate devices:

	iPulse Li ght IP L (HS- 650 & H S-300C)	**Accelawave S ystem**
510(k) reference	Current submission	K082484
Technology/ Operation/ Device description	Intense Pulsed Light (IPL)/broad spectrum light/touch screen operation.	Intense Pulsed Light (IPL)/broad spectrum light/touch screen operation.
Intended Use (wa velength/ E nergy see at tachment t ab le)	iPulseLight IPL System (HS 300C, HS 650) are identical with regard to indications for use including recommended filters to be used with Fitzpatrick skin type. Both models are intended for medical use in the treatment of the following dermatologic conditions: · Permanent hair reduction- long-term stable reduction in number of hairs re-growing after a treatment regimen. · Treatment of: - Moderate inflammatory acne vulgaris - Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles). - Cutaneous lesions including scars - Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, leg veins, spider anglomas and venous malformations. The integrated thermal cooling is indicated for use in cooling the epidermis at the treatment site prior to, during, and after light treatment in general aesthetic dermatologic and plastic surgery procedures. - Reduce pain during light treatment (via partial anesthesia from cooling) - Reduce discomfort during and/or associated with light treatment - Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light treatment, thus reducing possible complications such as scabbing, scarring, hyper - and/or hypo pigmentation - Allow the use of higher light or laser fluencies for light treatments (such as for hair removal and the treatment of vascular or pigmented lesions) - Reduce potential side effects of light treatments (such as for hair removal and the treatment of vascular or pigmented lesions)	Accelawave System is identical with regard to indications for use including recommended filters to be used with Fitzpatrick skin type. Both models are intended for medical use in the treatment of the following dermatologic conditions: · Permanent hair reduction- long-term stable reduction in number of hairs re-growing after a treatment regimen. · Treatment of: - Moderate inflammatory acne vulgaris - Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles). - Cutaneous lesions including scars - Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, leg veins and venous malformations. The integrated thermal cooling is indicated for use in cooling the epidermis at the treatment site prior to, during, and after light treatment in general aesthetic dermatologic and plastic surgery procedures. - Reduce pain during light treatment (via partial anesthesia from cooling) - Reduce discomfort during and/or associated with light treatment - Minimize thermal injury, including thermal necrosis, to non-target skin and skin s tructures during and/or associated with light treatment, thus reducing possible complications such as scabbing, scarring, hyper - and/or hypo pigmentation - Allow the use of higher light or laser fluencies for light treatments (such as for hair removal and the treatment of vascular or pigmented lesions) - Reduce potential side effects of light treatments (such as for hair removal and the treatment of vascular or pigmented lesions)
Wavelength Range	420-1200 nm	420-1200 nm
Energy ouput/ Setting Range	10-50 J/cm 2	10-50 J/cm 2
Pulse duration	5-50 ms	5-50 ms
Output Mode	Pulse method	Pulse method
Pulse width	2-20 ms	2-15 ms
Accessories	Foot switch Protection glasses Protection goggles	Foot switch Protection glasses Protection goggles
Deliver Materials	sapphire	sapphire

Max.power consumption	**1200W**	**1200W**
Applicator/hand-piece spot size	12x35mm and 15x 50mm	15x45mm
Charge time/ Repeat rate	1.5-2.0 Sec.	1.5-2.0 Sec.
Cooling method	Cooling handpiece by TE co oler an d Circulating water & Ai r	Cooling handpiece by TE co oler an d Circulating water & Ai r
Device classification	II; 21 CFR 878.4810, GEX	II; 21 CFR 878.4810, GEX

Intended use for Treatment region and dose rate.
iPulse Light IPL System(HS-650,HS-300C)

	FILTER SETTINGS and WAVELENGTH RANGE	SKIN TYPES					
CONDITIONS		I	II	III	IV	V	VI
Hair(course)		610~1200	610~1200	610~1200	640~1200	690~1200	N/A
Hair(fine)		610~1200	610~1200	610~1200	640~1200	690~1200	N/A
Acen Vulgaris		420~1200	420~1200	420~1200	510~1200	560~1200	N/A
Pigmented Epidermal Lesions							
a)Dyschromia		510~1200	510~1200	510~1200	560~1200	560~1200	N/A
b)Hyperpigmentation		510~1200	510~1200	510~1200	560~1200	560~1200	N/A
c)Melasma		560~1200	560~1200	560~1200	560~1200	560~1200	N/A
d)Ephelides		560~1200	560~1200	560~1200	560~1200	560~1200	N/A
Cutaneous Lesions							
Scars		560~1200	560~1200	560~1200	560~1200	560~1200	
Cutaneous Vascular Lesions							
a) Port Wine Stain (Child)		510~1200	510~1200	510~1200	560~1200	560~1200	N/A
b) Port Wine Stain (Adult)		510~1200	510~1200	510~1200	560~1200	560~1200	N/A
c) Hemangiomas		560~1200	560~1200	560~1200	560~1200	560~1200	N/A
d) Telaugiectasias		510~1200	510~1200	510~1200	560~1200	560~1200	N/A
e) Rosacea		560~1200	560~1200	560~1200	560~1200	560~1200	N/A
f) Spider Anglomas		560~1200	560~1200	560~1200	560~1200	560~1200	N/A
g) Venous Malformations		560~1200	560~1200	560~1200	560~1200	560~1200	N/A
Leg Veins							
a) Small		510~1200	510~1200	510~1200	560~1200	560~1200	N/A
b) Medium		560~1200	560~1200	560~1200	560~1200	560~1200	N/A
c) Large		560~1200	560~1200	560~1200	560~1200	N/A	N/A

Conclusion:
A comparison of the indications and the technical characteristics of the iPulse Light IPL System (HS-650, HS-300C) a
the legally marketed device including the Accelawave System, lead to the conclusion that the pertinent characteristic
the iPulse Light IPL system are substantially similar to the legally marketed devices. IN this capacity the iPulse
IPL System is substantially equivalent to device approved for marketing by the FDA and does not result in diffe
performance or raise new questions of safety or efficacy.

H. Performance Characteristics (If/when applicable)

The device complies with the European Medical Directive
Standards: 93/42/EEC concerning medical devices, and will comply with
voluntary standards ISO 60601-1 and ISO 60601-1-2: when marketed in the U.S.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 1 8 2011

Shanghali Apolo Medical Technologies Co., Ltd.
% Mr. Brandon Choi
Authorized Agent, General Manager
49 Candlewood Way
Buena Park, CA 90621

Re: K093627
Trade/Device Name: Ipulselight IPL System, Models HS 300C and HS 650
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: January 06, 2011
Received: January 11, 2011

Dear Mr. Choi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093627

p. 1 of 2

Indications for Use

510(k) Number (if known):

Device Name: iPulseLight IPL System (HS 300C, HS 650)

Indications For Use:

iPulseLight IPL System (HS 300C, HS 650) are identical with regard to indications for use including recommended filters to be used with Fitzpatrick skin type. Both models are intended for medical use in the treatment of the following dermatologic conditions:
· Permanent hair reduction- long-term stable reduction in number of hairs re-growing after a treatment regimen.
· Treatment of:

- Moderate inflammatory acne vulgaris
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- Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, leg veins, spider anglomas and venous malformations.

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K093627 p. 2 of 2

JAN 18 2011

		SKIN TYPES					
CONDITIONS	FILTER SETTINGS and WAVELENGTH RANGE	I	II	III	IV	V	VI
Hair(course)		610~1200	610~1200	610~1200	640~1200	690~1200	N/A
Hair(fine)		610~1200	610~1200	610~1200	640~1200	690~1200	N/A
Acne Vulgaris		420~1200	420~1200	420~1200	510~1200	560~1200	N/A
Pigmented Epidermal Lesions							
a)Dyschromia		510~1200	510~1200	510~1200	560~1200	560~1200	N/A
b)Hyperpigmentation		510~1200	510~1200	510~1200	560~1200	560~1200	N/A
c)Melasma		560~1200	560~1200	560~1200	560~1200	560~1200	N/A
d)Ephelides		560~1200	560~1200	560~1200	560~1200	560~1200	N/A
Cutaneous Lesions							
Scars		560~1200	560~1200	560~1200	560~1200	560~1200	
Cutaneous Vascular Lesions							
a) Port Wine Stain (Child)		510~1200	510~1200	510~1200	560~1200	560~1200	N/A
b) Port Wine Stain (Adult)		510~1200	510~1200	510~1200	560~1200	560~1200	N/A
c) Hemangiomas		560~1200	560~1200	560~1200	560~1200	560~1200	N/A
d) Telaugiectasias		510~1200	510~1200	510~1200	560~1200	560~1200	N/A
e) Rosacea		560~1200	560~1200	560~1200	560~1200	560~1200	N/A
f) Spider Anglomas		560~1200	560~1200	560~1200	560~1200	560~1200	N/A
g) Venous Malformations		560~1200	560~1200	560~1200	560~1200	560~1200	N/A
Leg Veins							
a) Small		510~1200	510~1200	510~1200	560~1200	560~1200	N/A
b) Medium		560~1200	560~1200	560~1200	560~1200	560~1200	N/A
c) Large		560~1200	560~1200	560~1200	560~1200	N/A	N/A

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic
and Restorative Devices

510(k) Number K093627